Atty's Docket: 101141-12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO.	09/979,513
APPLICANT	Peter DANIEL et al.,
FILED	25 February 2002
EXAMINER	Jeanine Anne Goldberg
ART UNIT	1634
FOR	METHOD FOR DETECTING THE EFFECT OF DIFFERENT CHEMOTHERAPEUTIC AGENTS

Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

13 January 2004

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This communication is responsive to the to office action dated 17 July 2003.

Consideration of the remarks is respectfully requested.

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CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

REMARKS

The claims have been restricted into two groups.

In response, Applicants provisionally elect with traverse, group I, and p53 for examination.

Arguments in Support of Traversal

The claims are directed to a method of determining the effect of chemotherapeutic agents and radiation, as a function of the expression profiles of apoptosis and cell growth regulating genes. In other words, the claimed method is directed to interpreting the results of a spectrum of tests and integrating the results into a treatment profile for cancer patients.

"Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features." See Annex B. In the present claims, each marker bears directly on the treatment profile obtained. In this respect, each marker, regardless of how it is assayed, indeed shares the same special technical feature.

Therefore, the special technical relationship under PCT 13.2 is the contribution of each genetic entity to a particular regimen of chemo/radiotherapy.

The technical features of the claimed method has little or nothing to do with how the marker level is determined. In other words, it is irrelevant whether a particular genetic marker is determined by protein or nucleic acid methodology.

For example, Applicants elected p53 for examination. The endpoint is whether or not the effect of the treatment was to increase or decrease the activity or levels of p53. But it is not relevant to the claimed method whether that result is obtained from an immunological assay or PCR. That is because either assay provides a result sharing the same special technical feature -- i.e., that it contributes to the genetic profile of apoptotic and growth related genes.

Thus, Examiner's intent to restrict the claimed method between a protein based measurement and a nucleic acid based measurement is not proper under PCT unity of invention standards. In essence, Examiner seems to have conceptually divided the claimed method of determining a gene profile of treatment responsiveness into separate methods of analyzing individual components, without considering Applicants' emphasis on their combined value.

Respectfully, this is not proper and the restriction requirement should be withdrawn.

Cited Prior Art

Examiner also asserts that the claims do not provide a contribution over the art. The reference to Tai is cited.

First, whereas Tai employs a single genetic marker in ovarian cell lines. In contrast, the claims recite methods of analysis in patients. Respectfully, it is long held PTO policy that *in vivo* studies, *especially human studies*, are patentably distinct from those performed *in vitro*. Further, the claimed method is supported by the specification and experimental results provided therein.

In addition, Lowe by itself cannot render the claimed method unpatentable. As Examiner states, Lowe shows that "p53 may be an important determinant...."

However, this still cannot render the claims unpatentable as the claimed method is distinct from what this conclusion stands for.

Third, it is irrelevant that methods for detecting different genes are patentably distinct from each other because the claims do not seek to patent *any* method of detecting *any* genes.

Examiner's statement that each gene requires a separate search is also irrelevant and forms an improper basis to conclude patentability issues of the instant claims. The search of the art must involve how a treatment profile of apoptotic/growth regulating genes correlates with outcome of the treatment. Searching the actual methods of detecting is irrelevant as these individual methods are not *per se*, being claimed.

CONCLUSION

In view of the foregoing remarks it is respectfully requested that the restriction requirement be withdrawn.

Respectfully Submitted,

Norris, McLaughlin & Marcus
220 East 42 nd Street
New York, NY 10017
Telephone (212) 808-0700
Facsimile (212) 808-0844

Theodore Gottlieb,PhD
Reg. No. 42, 597

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